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PPTA
Plasma Protein Therapeutics Association

PPTA Statement on Contribution of Manufacturing Processes to Prion Removal in the Production of Plasma-derived Therapeutics

FDA TSE Advisory Committee Meeting

12 February 2004

The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies, immunoglobulins, therapies for alpha-1 anti-trypsin deficiency, and albumin.

An abundance of data published in the scientific literature within the last five years on investigation of prion removal demonstrate significant clearance of infectivity in several of the manufacturing steps in the plasma fractionation process. In addition, PPTA member companies have generated unpublished data demonstrating the partitioning capacity of the manufacturing process, which have been shared with the TSE Advisory Committee in the past and most recently with the TSE Expert Group of the European Union Committee for proprietary medicinal products (CPMP).

It can be concluded from this large body of published and unpublished evidence that significant prion removal has been demonstrated convincingly and reproducibly for many common procedures used in the manufacturing process of plasma derivatives. Although prion removal is process-specific and manufacturer-specific, because it is context specific, available data demonstrate that prion removal is independent of the prion strain evaluated or the assay system used for detection or of the prion spike or its titer. Prion removal can be different for different spike preparations in some steps, but nevertheless the reduction factors are remarkably consistent for most product categories. Additionally, prion removal by a series of processing steps can be additive.

PPTA has ongoing research activities with regard to TSEs, and PPTA and its members are committed to keeping the vCJD issue a high priority as we continue in our mission to ensure the safety and availability of the life-saving medicines we manufacture. As a part of the Association's ongoing research efforts mentioned above, PPTA has commenced a collaborative study to investigate the inactivation capacity of the most commonly used sanitization solutions to generate a comprehensive and yet unavailable data set on which the member companies will base their study designs for the individual cleaning and sanitization procedures.

PPTA and its members remain confident that the plasma derived medicinal products they manufacture are safe, pure, and efficacious.

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